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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,504	05/06/2004	Rafail Zubok	532-3X4	2919
530 7590 01/16/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER SCHILLINGER, ANN M	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 01/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,504

Applicant(s)

ZUBOK ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/31/07
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Branch et al. (US Pat. No. 6,174,311). Branch et al. discloses the following: removing a portion of the intervertebral disc (col. 18, lines 9-36); an insertion plate (152), comprising: a base (proximal end of element 152); a first mounting element (160) of the base operable to engage a first member (124) of an intervertebral disc replacement device (110); a second mounting element (170) of the base operable to engage a second member (126) of the intervertebral disc replacement device, wherein the first and second mounting elements cooperate to engage and orient the first and second members of the intervertebral disc replacement device for simultaneous insertion into an intervertebral disc space of a spinal column (see Figures 17-21; col. 11, lines 16-37); and a stem (184) extending away from an anteriorly directed surface of the base and operable to facilitate movement of the intervertebral disc replacement device and insertion thereof into the intervertebral disc space such that the first and second members may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another, the stem being sized and shaped for engagement with an insertion handle (151, 180) to further facilitate movement of the intervertebral disc replacement device, wherein one of the stem and the insertion handle includes

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a bore and the other of the stem and the insertion handle includes a tapered shaft that frictionally engages the bore to facilitate detachable engagement with one another (col. 11, lines 39-57).

Branch et al. also discloses the insertion plate having a ledge member (162, 166 and 168, 172) that will engage the intervertebral disc replacement device, where the upper ledge has a curved shape, and the lower ledge has a flat shape. The insertion plate may be removed from the intervertebral replacement device after it has been coupled to the vertebral bones (col. 10, lines 14-37).

Please note that it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, 7, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branch et al. in view of Michelson (US Pub. No. 2002/0004683). Branch et al. discloses the invention substantially as claimed, however, Branch et al. does not disclose the mounting elements and the intervertebral disc replacement device having holes for fasteners. Michelson teaches a spinal implant tool where the mounting elements and the intervertebral disc replacement device have holes for fasteners in paragraphs 0006-0013 and 0066-0075 for the

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purpose of better securing the intervertebral disc replacement device to the mounting elements. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mounting elements and the intervertebral disc replacement device with holes for fasteners in order to better secure the intervertebral disc replacement device to the mounting elements.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Branch et al. in view of Sanderson (U.S. Pat. No. 4,105,407). Branch et al. does not disclose the implant as being in a sterile package. Sanderson teaches a sterilization technique for medical devices in col. 2, lines 54-56 for the purpose of safeguarding the patient by preventing infection. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to make the implant part of a sterile assembly package to safeguard the patient by preventing infection.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Branch et al. Branch et al. discloses the claimed invention except for the handle being detachable from the insertion plate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the handle detachable from the insertion plate, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 13-17, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
January 10, 2008


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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